UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

Ex parte PREETI LAI,
JENNIFER L. HILLMAN,
HENRY YUE, KARL J. GUGLER,
NEIL C. CORLEY, OLGA BANDMAN,
CHANDRA PATTERSON, GINA A. GORGONE,
MATTHEW R. KASER, MARIAH R. BAUGHN, and
JANICE AU-YOUNG

Appeal No. 2006-1274
Application No. 09/700,590

ON BRIEF

Before SCHEINER, GRIMES, and LEBOVITZ, Administrative Patent Judges.

GRIMES, Administrative Patent Judge.

DECISION ON APPEAL

This appeal involves claims to nucleic acids encoding a human transmembrane protein, which the examiner has rejected as lacking patentable utility, nonenablement, and inadequate written description. We have jurisdiction under 35 U.S.C. § 134. We affirm.

Background

The specification discloses "nucleic acid and amino acid sequences of human transmembrane proteins." Page 1. The amino acid sequences of seventy-nine "human

transmembrane proteins, referred to collectively as 'HTMPN'," are set out in SEQ ID NOs 1 through 79 of the Sequence Listing. The instant claims concern nucleic acids that encode the polypeptide having the amino acid sequence shown in SEQ ID NO:22, which is referred to in the specification as "HTMPN-22."

The specification discloses that HTMPN-22 was isolated from the cDNA library BRAITUT02 (see page 73); that HTMPN-22 has 688 amino acid residues, twenty-nine potential phosphorylation sites, four potential glycosylation sites, two "Signature Sequence[s]" ("S5-G8" and "A80-N140"), and is similar to "Ring3" (see page 79); and that HTMPN-22 is expressed in a certain percentage of libraries associated with different types of tissues and conditions (see page 88). The specification does not disclose any biological function or activity for HTMPN-22.

The specification discloses that "[m]embranes contain ion pumps, ion channels, and specific receptors for external stimuli. . . . [M]embranes also contain second messenger proteins that interact with these pumps, channels and receptors." Page 1. The specification discloses that transmembrane proteins include

- G-protein coupled receptors, which "include receptors for biogenic amines, lipid mediators of inflammation, peptide hormones, and sensory signal mediators";
- scavenger receptors that "may participate in the binding of low density lipoproteins (LDL) and foreign antigens";
- the transmembrane 4 or tetraspan family, which includes "platelet and endothelial cell membrane proteins, melanoma-associated antigens, leukocyte surface glycoproteins, colonal carcinoma antigens, tumor-associated antigens, and surface proteins of the schistosome parasites";
- tumor antigens;
- ion channels;

• proton pumps, "a large class of membrane proteins that . . . generate an electrochemical proton gradient across a membrane";

• ATP-binding cassette transporters, "a superfamily of membrane proteins that mediate transport and channel functions in prokaryotes and eukaryotes";

• proteins involved with exocytosis and endocytosis, and those associated with lysosomes and peroxisomes;

• endoplasmic reticulum membrane proteins;

• mitochondrial membrane proteins;

• lymphocyte and leukocyte membrane proteins; and

• membrane proteins associated with apoptosis and tumorigenesis.

See pages 3-10.

Discussion

1. Claims

Claims 23-29 and 31 are on appeal. Claims 21, 22, 30, and 32-40 are also pending but have been withdrawn from consideration by the examiner.

The claims subject to each rejection stand or fall together. See the Appeal Brief, pages 3-4. We will focus on claim 23, the broadest claim on appeal. Claim 23 depends on claim 21. Claims 21 and 23 read as follows:

21. An isolated polypeptide selected from the group consisting of:

a) a polypeptide comprising the amino acid sequence of SEQ ID NO:22

b) a polypeptide comprising a naturally occurring amino acid sequence at least 90 % identical to the amino acid sequence of SEQ ID NO:22,

c) a biologically active fragment of a polypeptide having the amino acid sequence of SEQ ID NO:22, and

d) an immunologically active fragment of a polypeptide having the amino acid sequence of SEQ ID NO:22, wherein said immunologically active fragment generates an antibody that specifically binds to SEQ ID NO:22.

23. An isolated polynucleotide encoding a polypeptide of claim 21.

Thus, claim 23 is directed to a polynucleotide (i.e., RNA or DNA) that encodes (a) a polypeptide comprising the amino acid sequence of SEQ ID NO:22, (b) a naturally occurring polypeptide that is at least 90% identical to SEQ ID NO:22, or (c) a biologically or immunologically active fragment of the polypeptide of SEQ ID NO:22.

2. Lack of utility

The examiner rejected claims 23-29 and 31 under 35 U.S.C. §§ 101 and 112, first paragraph, on the basis that the specification does not disclose a patentable utility for the claimed polynucleotides. See the Examiner's Answer, pages 4 and 7.

The examiner bears the initial burden of showing that a claimed invention lacks patentable utility. See In re Brana, 51 F.3d 1560, 1566, 34 USPQ2d 1436, 1441 (Fed. Cir. 1995) ("Only after the PTO provides evidence showing that one of ordinary skill in the art would reasonably doubt the asserted utility does the burden shift to the applicant to provide rebuttal evidence.").

The U.S. Court of Appeals for the Federal Circuit recently addressed the utility requirement in the context of a claim to DNA. See In re Fisher, 421 F.3d 1365, 76 USPQ2d 1225 (Fed. Cir. 2005). The Fisher court interpreted Brenner v. Manson, 383 U.S. 519, 148 USPQ 689 (1966), as rejecting a "de minimis view of utility." 421 F.3d at 1370, 76 USPQ2d at 1229. The Fisher court held that § 101 requires a utility that is both substantial and specific. Id. at 1371, 76 USPQ2d at 1229. The court held that

disclosing a substantial utility means "show[ing] that an invention is useful to the public as disclosed in its current form, not that it may be useful at some future date after further research. Simply put, to satisfy the 'substantial' utility requirement, an asserted use must show that that claimed invention has a significant and presently available benefit to the public." Id., 76 USPQ2d at 1230.

The court held that a specific utility is "a use which is not so vague as to be meaningless." Id. In other words, "in addition to providing a 'substantial' utility, an asserted use must show that that claimed invention can be used to provide a well-defined and particular benefit to the public." Id.

The Fisher court held that none of the uses asserted by the applicant in that case were either substantial or specific. The uses were not substantial because "all of Fisher's asserted uses represent merely hypothetical possibilities, objectives which the claimed ESTs, or any EST for that matter, could possibly achieve, but none for which they have been used in the real world." Id. at 1373, 76 USPQ2d at 1231. "Consequently, because Fisher failed to prove that its claimed ESTs can be successfully used in the seven ways disclosed in the '643 application, we have no choice but to conclude that the claimed ESTs do not have a 'substantial' utility under § 101." Id. at 1374, 76 USPQ2d at 1232.

"Furthermore, Fisher's seven asserted uses are plainly not 'specific.' Any EST transcribed from any gene in the maize genome has the potential to perform any one of the alleged uses. . . . Nothing about Fisher's seven alleged uses set the five claimed ESTs apart from the more than 32,000 ESTs disclosed in the '643 application or indeed from any EST derived from any organism. Accordingly, we conclude that Fisher has only disclosed general uses for its claimed ESTs, not specific ones that satisfy § 101." Id.

In this case, the examiner found the "claims are drawn to an invention with no apparent or disclosed patentable utility. The instant application has provided a partial description of the isolated protein in the form of a predicted amino acid sequence. However, the application does not disclose the physical or structural properties of this protein. In addition, the instant application does not disclose the biological role of this protein or its significance." Examiner's Answer, page 4. The examiner also pointed out that "the [poly]nucleotides of the instant invention have not been linked to a disease state [or] methods of treating diseases listed in [the specification] page 37, line 25 to page 40, line 12." Id., page 6.

Appellants argue that the claimed polynucleotides have patentable utility because the polypeptide of SEQ ID NO:22 is similar to the mouse Ring3 protein. See the Appeal Brief, page 34: "HTMPN-22 has 57% homology over 548 amino acid residues to mouse Ring3." Appellants also argue that sequence analysis "demonstrates the presence of a bromodomain, a domain found in various transcriptional regulators, from residues A80-N140. This region is shown as a signature sequence in column 5 of Table 2 (see page 79 of the specification). Thus the specification identified HTMPN-22 as a Ring3-related bromodomain protein." Id.

Appellants reason that Ring3 was known, as of the instant application's effective filing date, to be a "nuclear serine-threonine kinase" and that the "human Ring3 kinase was known to be very active in leukocytes of patients with acute and chronic leukemias." Id., citing Ostrowski.[1] Appellants cite Ostrowski's statements that the

[1] Ostrowski et al., "Stimulation of p85/RING3 kinase in multiple organs after systemic administration of mitogens into mice," Oncogene, Vol. 16, pp. 1223-1227 (March 1998).

"results of these studies may reflect involvement of p85/RING3 kinase in diseases where abnormal cell proliferation is responsible for the pathological process" (sentence bridging pages 1226 and 1227) and assert that "one skilled in the art would have understood that HTMPN[-22] had significant homology to a Ring3, a protein with a known role in cell proliferative and immune disorders." Appeal Brief, page 35.

Appellants argue that the similarity of HTMPN-22 to mouse Ring3 is "more than enough . . . to demonstrate a reasonable probability that the utility of Ring3 can be imputed to the claimed invention." Id. Appellants conclude that "a person of ordinary skill in the art would recognize more than a reasonable probability that the polypeptide encoded for by the claimed invention has utility similar to Ring3." Id., page 34.

We do not agree that the claimed polynucleotides have utility based on the similarity of the encoded polypeptide to mouse Ring3. Appellants rely on Brenner[2] for the proposition that "[i]t is well known that the probability that two unrelated polypeptides share more than 40% sequence homology over 70 amino acid residues is exceedingly small." While this proposition may be true, and we will accept it as such for present purposes, it does not support the weight Appellants put on it.

That is, the degree of sequence similarity between HTMPN-22 and mouse Ring3 may well indicate that the genes encoding the two polypeptides are related, in the evolutionary sense, meaning that the two genes shared a single common ancestral gene at some point in the past. Based on that "relatedness," it may be reasonable to expect that HTMPN-22 is a kinase, perhaps even a nuclear serine-threonine kinase like Ring3.

---

[2] Brenner et al., "Assessing sequence comparison methods with reliable structurally identified distant evolutionary relationships," Proc. Natl. Acad. Sci. USA, Vol. 95, pp. 6073-6078 (1998).

What HTMPN-22 is not, however, is the human homolog of mouse Ring3. Thorpe discloses the complete amino acid sequence of human Ring3, and compares that sequence to that of mouse Ring3.[3] See Figure 3. Thorpe discloses that the mouse and human Ring3 sequences are both 805 amino acids in length and are 96.4% identical in sequence. See Figure 3 and page 83, right-hand column. The evidence of record, on the other hand, shows that HTMPN-22 is 688 amino acids long and is only 57% identical to mouse Ring3 over part (548 amino acids) of its sequence. Thus, HTMPN-22 is not human Ring3, meaning that it is not the polypeptide said by Ostrowski to be "very active in leukocytes of patients with acute and chronic leukemias."

In conclusion, we agree with Appellants that it is reasonable to conclude that HTMPN-22 is somehow related to mouse Ring3, based on their sequence similarity.[4] However, we disagree that that sequence similarity, and the relatedness that it implies, establishes the patentable utility of the claimed polynucleotides.

Appellants also argue that the claimed polynucleotides have "numerous practical, beneficial uses in toxicology testing, drug development, and the diagnosis of disease, none of which requires knowledge of how the polypeptide coded for by the polynucleotide actually functions." Appeal Brief, page 5. Appellants have provided a declaration under 37 CFR § 1.132 by Dr. Tod Bedilion (filed June 24, 2003) to support

---

[3] Thorpe et al., "DNA sequence and structure of the mouse RING3 gene: identification of variant RING3 transcripts," Immunogenetics, Vol. 48, pp. 82-86 (1998). A copy of Thorpe is included with this opinion.

[4] We have not considered the post-filing references purportedly showing that HTMPN-22 is similar to "the short form of human Brd4." See the Appeal Brief, pages 36-37. Utility is determined as of the effective filing date of the application. See Brana, 51 F.3d at 1567 n.19, 34 USPQ2d at 1441 n.19. Appellants have provided no evidence to show that those skilled in the art, at the time this application was filed, would have been aware of any similarity between HTMPN-22 and human Brd4.

their position that the claimed polynucleotides could be used in gene expression monitoring applications.[5]

Appellants argue, in a nutshell, that "all polynucleotides expressed in humans have utility in toxicology testing based on the property of being expressed at some time in development or in the cell life cycle," Appeal Brief, page 26, because a potential drug that affects the expression of genes other than its intended target (including, for example, the gene encoding SEQ ID NO:22) might cause undesirable side effects. See the Appeal Brief, pages 32-33. Thus, the argument goes, the more genes that a gene expression-monitoring microarray includes, the more information it can potentially provide regarding the effect of a candidate drug on genes that are not intended to be affected. See id., page 13 ("[T]he person of ordinary skill in the art can derive more information about a potential drug candidate . . . with the claimed invention than without it.").

We do not agree that using the claimed polynucleotides to monitor the cellular expression of the corresponding gene constitutes a specific and substantial utility, as those terms were defined by the Fisher court. Like the generic utilities asserted in Fisher, Appellants' asserted uses for the claimed polynucleotides in monitoring gene expression in "toxicology testing, drug development, and disease diagnosis" are neither substantial nor specific. Just as in Fisher, these uses are "merely hypothetical possibilities, objectives which the claimed [cDNAs], or any [cDNA] for that matter, could possibly achieve, but none for which they have been used in the real world." Fisher,

[5] Appellants submitted three additional declarations under Rule 132, along with ten references, together with the Appeal Brief. See the Appeal Brief, page 6. The examiner refused to enter the declarations or references. Examiner's Answer, page 16. Therefore, we have not considered them.

421 F.3d at 1373, 76 USPQ2d at 1231 (emphasis in original). Therefore, they are not substantial utilities.

Nor are they specific utilities, because they could be asserted for any cDNA transcribed from any gene in the human genome. Appellants have asserted as much. See the Appeal Brief, page 26 ("all polynucleotides expressed in humans have utility in toxicology testing"). Because nothing about Appellants' asserted utilities sets the claimed nucleic acids apart from any other human cDNA, Appellants have "only disclosed general uses for [the] claimed [cDNAs], not specific ones that satisfy § 101." Id. at 1374, 76 USPQ2d at 1232.

Appellants have not disclosed any specific and substantial utility for the claimed polynucleotides. We therefore affirm the rejection of claims 23-29 and 31 under 35 U.S.C. § 101. As a result, we also affirm the rejection of these claims under 35 U.S.C. § 112, first paragraph, for nonenablement. See Fisher, 421 F.3d at 1378, 76 USPQ2d at 1235 ("It is well established that the enablement requirement of § 112 incorporates the utility requirement of § 101.").

3. Nonenablement

The examiner also rejected claims 23, 26-29 and 31 under 35 U.S.C. § 112, first paragraph, "because the specification, were it enabling only for[ ] an isolated polynucleotide . . . encoding SEQ ID NO:22 . . . would still not be enabling for sequences of limited homology to . . . SEQ ID NO:22 or sequences comprising fragments of . . . SEQ ID NO:22, with no functional limitation." Examiner's Answer, page 7.

As we understand it, the basis for this rejection is that, even if the polypeptide of SEQ ID NO:22 were found to have utility, the specification's guidance does not enable those skilled in the art to practice the full scope of the claimed 90% identical sequences and biologically or immunologically active fragments without undue experimentation. Since we have already concluded that the specification does not disclose a patentable utility for the claimed polynucleotides, and therefore does not enable those skilled in the art to use anything within the scope of the claims without undue experimentation, we need not address the alternative basis for rejecting claims 23, 26-29, and 31.

4. Written description

The examiner rejected claims 23, 26-29 and 31 under 35 U.S.C. § 112, first paragraph, on the basis that the specification does not provide an adequate written description of the claimed polynucleotides. The examiner acknowledged that the specification adequately describes nucleotide sequences encoding the amino acid sequence of SEQ ID NO:22 but concluded that claim 23 as a whole lacked adequate description because the specification does not adequately describe the claimed polynucleotides encoding "a polypeptide comprising a naturally occurring amino acid sequence at least 90% identical to the amino acid sequence of SEQ ID NO:22." Examiner's Answer, page 10.[6]

The examiner reasoned that "without having a written description of all naturally occurring sequences within the metes and bounds of the claims, one would not be

[6] The examiner also rejected the claims as being based on an inadequate description of "biologically active fragments" and "immunogenic fragments" of SEQ ID NO:22. Since we conclude that the specification does not adequately describe the claimed naturally occurring variants, however, we need not consider whether the descriptions of biologically active fragments and immunogenic fragments meet the requirements of § 112.

capable of determining whether or not a given species was claimed." Id., page 55. That is,

> [o]ne could certainly determine whether a protein that one had obtained from nature w[as] 90% identical to SEQ ID NO:22, but that same person, handed a protein in a test tube, would have no way of determining whether that protein w[as] "naturally occurring". . . . Page 15 of the specification merely defines what an allelic variant is. It does not describe even a single naturally occurring allelic variant.

Id.

We agree with the examiner that the instant specification does not describe the claimed genus of polynucleotides that encode "a naturally occurring amino acid sequence at least 90% identical to the amino acid sequence of SEQ ID NO:22." The specification discloses the amino acid sequence of SEQ ID NO:22 and one DNA sequence that encodes it (SEQ ID NO:101). That disclosure is adequate to describe all of the DNA sequences that encode the amino acid sequence of SEQ ID NO:22. See In re Wallach, 378 F.3d 1330, 1333, 71 USPQ2d 1939, 1942 (Fed. Cir. 2004) ("[T]he state of the art has developed such that the complete amino acid sequence of a protein may put one in possession of the genus of DNA sequences encoding it.").

Claim 23, however, is not limited to polynucleotides encoding the amino acid sequence of SEQ ID NO:22. Appellants also claim polynucleotides encoding "a naturally occurring amino acid sequence at least 90% identical to the amino acid sequence of SEQ ID NO:22." That is, the claimed polynucleotides are defined by two characteristics: (1) they are naturally occurring, and (2) they encode amino acid sequences that are at least 90% identical to SEQ ID NO:22.

This appeal does not require us to decide whether the disclosure of an amino acid sequence describes all the DNAs that encode amino acid sequences that are, e.g., 90% identical to the disclosed sequence. For present purposes, however, we will assume that disclosure of SEQ ID NO:22 (which adequately describes all DNAs that encode SEQ ID NO:22) is adequate to describe all DNAs that encode sequences that are 90% identical to SEQ ID NO:22

The critical question then, is this: assuming that the specification's disclosure is adequate to describe a genus of DNAs (i.e., that that encode sequences at least 90% identical to SEQ ID NO:22), is that same disclosure adequate to describe a subset of those DNAs (i.e., the encoding naturally occurring sequences), even without any disclosure of which members of the large genus are included in the subgenus?

We conclude that a describing a genus of chemical compounds is not necessarily adequate to support a claim limited to only those compounds that have a desired characteristic. Rather, the specification must provide guidance regarding which compounds within the genus have the recited characteristic.

The U.S. Court of Appeals for the Federal Circuit, faced with circumstances similar to those here, has held claims to lack adequate description. For example, in University of California v. Eli Lilly and Co., 119 F.3d 1559, 43 USPQ2d 1398 (Fed. Cir. 1997), the court held that claims generically reciting cDNA encoding vertebrate or mammalian insulin were not adequately described by the disclosure of cDNA encoding rat insulin. Id. at 1568, 43 USPQ2d at 1406. The court held that

> a generic statement such as "vertebrate insulin cDNA" or "mammalian insulin cDNA," without more, is not an adequate written description of the genus because it does not distinguish the genus from others, except by

> function. It does not specifically define any of the genes that fall within its definition. It does not define any structural features commonly possessed by members of the genus that distinguish them from others. One skilled in the art therefore cannot, as one can do with a fully described genus, visualize or recognize the identity of the members of the genus.

Id. The court described two ways of properly describing a claimed genus:

> A description of a genus of cDNAs may be achieved by means of a recitation of a representative number of cDNAs, defined by nucleotide sequence, falling within the scope of the genus or of a recitation of structural features common to the members of the genus, which features constitute a substantial portion of the genus.

Id. The court has since clarified that the description of representative species does not necessarily have to include their complete structure (nucleotide sequence). See Enzo Biochem, Inc. v. Gen-Probe Inc., 323 F.3d 956, 964-65, 63 USPQ2d 1609, 1613 (Fed. Cir. 2002).

The holding of Eli Lilly supports our conclusion that the instant specification does not adequately describe the claimed genus of DNAs – those that encode naturally occurring sequences at least 90% identical to SEQ ID NO:22. The Eli Lilly court held that a fully described genus is one for which a person skilled in the art can "visualize or recognize the identity of the members of the genus." Here, as the examiner has pointed out, the specification provides no description of DNAs that encode naturally occurring variants of SEQ ID NO:22 that would allow a person skilled in the art to determine whether a given DNA encoding an amino acid sequence at least 90% identical to SEQ ID NO:22 is within the scope of the instant claims.

The recitation of "naturally occurring" sequences does not imply any structural features that would distinguish the claimed DNAs from non-naturally occurring DNAs. Since the specification does not describe the claimed DNAs adequately for those skilled

in the art to distinguish the claimed DNAs from other DNAs, the specification does not adequately describe the claimed DNAs under the standard of Eli Lilly.[7]

The court also confronted facts similar to those here in University of Rochester v. G.D. Searle & Co., Inc., 358 F.3d 916, 69 USPQ2d 1886 (Fed. Cir. 2004). In that case, the patent claimed a method of selectively inhibiting the enzyme PGHS-2 (also known as COX-2) by "administering a non-steroidal compound that selectively inhibits activity of the PGHS-2 gene product to a human." Id. at 917, 69 USPQ2d at 1888. The patent "described in detail how to make cells that express either COX-1 or COX-2, but not both . . . , as well as 'assays for screening compounds, including peptides, polynucleotides, and small organic molecules to identify those that inhibit the expression or activity of the PGHS-2 gene product.[']" Id. at 927, 69 USPQ2d at 1895.

The court held that the disclosure of screening assays and general classes of compounds was not adequate to describe compounds having the desired activity: without disclosure of which peptides, polynucleotides, or small organic molecules have the desired characteristic, the claims failed to meet the description requirement of § 112. See id. ("As pointed out by the district court, the '850 patent does not disclose just 'which "peptides, polynucleotides, and small organic molecules" have the desired

[7] Our conclusion is also consistent with the Eli Lilly court's treatment of claims directed to cDNA encoding human insulin. The court noted that a description that merely renders obvious a claimed invention does not describe that invention adequately to satisfy 35 U.S.C. § 112, first paragraph, and that a claim to a specific DNA is not made obvious by knowledge of the encoded protein sequence and a method of obtaining the DNA. 119 F.3d at 1567, 43 USPQ2d at 1405 (citing Lockwood v. American Airlines, Inc., 107 F.3d 1565, 41 USPQ2d 1961 (Fed. Cir. 1997), and In re Deuel, 51 F.3d 1552, 34 USPQ2d 1210 (Fed. Cir. 1995)). The Eli Lilly court concluded that "a fortiori, a description that does not render a claimed invention obvious does not sufficiently describe that invention for purposes of § 112, ¶ 1." Id. The same conclusion logically applies when the claim is directed to a genus of naturally occurring DNA sequences rather than a single naturally occurring sequence.

characteristic of selectively inhibiting PGHS-2.' . . . Without such disclosure, the claimed methods cannot be said to have been described.").

Just as in University of Rochester, the present application discloses a broad genus of chemical compounds (DNAs encoding amino acid sequences at least 90% identical to SEQ ID NO:22) but the claims are limited to only those compounds having a desired characteristic (encoding naturally occurring sequences). Just as in University of Rochester, the present specification does not disclose which of the many possible DNAs that encode amino acid sequences at least 90% identical to SEQ ID NO:22 encode naturally occurring sequences.

Granted, those skilled in the art could screen libraries of naturally occurring DNAs to identify for themselves specific DNAs that encode naturally occurring amino acid sequences at least 90% identical to SEQ ID NO:22. That, however, does not make up for the deficiency of the specification's description. The University of Rochester court specifically noted that the patent at issue there disclosed screening assays to identify compounds having the desired characteristic, but nonetheless held that the description was inadequate. The same holds true here.

Appellants argue that "[v]ariants of SEQ ID NO:22 having 90% amino acid identity to SEQ ID NO:22 are described, for example, at page 11, lines 30-32. Polynucleotide variants having 90% polynucleotide sequence identity to the polynucleotide encoding SEQ ID NO:22 are described, for example, at page 12, lines 3-6. . . . Given SEQ ID NO:22 and SEQ ID NO:101, one of ordinary skill in the art would recognize naturally occurring variants . . .encoding amino acid sequences having 90% identity to SEQ ID NO:22." Appeal Brief, pages 49-50. Appellants also argue that the

"specification discloses how to calculate the % identify between two sequences . . . , allowing one of skill in the art to determine which naturally occurring sequences are encompassed by the claims." Id., page 50.

This argument is not persuasive. The cited passages from the specification (pages 11 and 12) merely recite the same words used in the claims. They do not disclose the structure of any DNAs within the scope of the claim. Further, as discussed above, the court in University of Rochester made clear that § 112 requires a description of which compounds have the desired characteristic recited in the claims, not simply a description of methods by which those skilled in the art can test compounds to see if they are encompassed by the claims. Because the instant specification provides no description of which DNAs encoding amino acid sequences at least 90% identical to SEQ ID NO:22 encode naturally occurring sequences, the instant specification does not provide the required description.

Appellants also argue that Eli Lilly is distinguishable from the instant case, in the nucleic acids in that case "were defined on the basis of functional characteristics," while "the claims at issue in the present application define polynucleotides in terms of chemical structure." Appeal Brief, pages 52-53.

We are not persuaded by this argument. Although the claimed genus of DNAs is defined in part by structure, it is also defined by the nonstructural characteristic of encoding a naturally occurring sequence. Thus, the specification must describe the claimed genus sufficiently to allow those skilled in the art to distinguish the claimed DNAs from those that are structurally distinct, and also from those that encode non-naturally occurring amino acid sequences at least 90% identical to SEQ ID NO:22.

We have considered the other arguments that Appellants raised in response to this rejection but do not find them persuasive. For the reasons discussed above, the rejection of claims 23, 26-29 and 31 for lack of adequate written description is affirmed.

Summary

We affirm the rejections based on lack of patentable utility because the specification does not disclose a specific and substantial utility for the claimed polynucleotides. We affirm the rejection based on lack of adequate written description because the specification does not describe which DNAs encoding amino acid sequences at least 90% identical to SEQ ID NO:22 are naturally occurring.

No time period for taking any subsequent action in connection with this appeal may be extended under 37 CFR § 1.136(a).

AFFIRMED

Toni R. Scheiner)
Administrative Patent Judge)
)
)
) BOARD OF PATENT
Eric Grimes)
Administrative Patent Judge) APPEALS AND
)
) INTERFERENCES
)
Richard M. Lebovitz)
Administrative Patent Judge)

EG/jlb

Foley and Lardner, LLP
3000 K Street, N.W.
Suite 500
Washington, DC 20007